K011844

AUG 2 8 2001

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY"

9.1	Submitter:	P/L Biomedical 7690 Cameron Circle Fort Myers, FL 33912 Tel - 941-768-1118 Fax - 815-550-0162 Contact - Lee Leichter Prepared - August 7, 2001
9.2	Trade/Proprietary Name:	Merits Health Products Oxygen Concentrators
9.3	Common/Usual Name:	Oxygen Concentrator
9.4	Classification Name:	Portable Oxygen Generator

9.5 Comparison to Currently Marketed Devices

The Merits Health Products Oxygen Concentrators are substantially equivalent to the OxLife Concentrators (K955549 and K971964), AirSep NewLife Oxygen Concentrators (Last Submission - K960309) and Invacare Oxygen Concentrators (K904087).

9.6 Device Description

The Merits Health Products Oxygen Concentrators are prescription devices designed to provide an inexpensive supply of supplemental oxygen in a home or institution without a continuous source of purified oxygen. They are not life-supporting nor life-sustaining devices. The devices operate through the use of molecular sieve material that binds with the water and nitrogen in filtered room air to leave a gas that is approximately 93% oxygen when delivered to the patient. The compressor creates a vacuum to draw room air into a holding tank. At the same time, downstream of the compressor, the air from the previous cycle is pressurized into one of the two aluminum welded molecular sieve tanks. As the oxygen is forced out of the end of the tank, it enters a 'T' fitting that directs most of the gas to flush the nitrogen out of the second molecular sieve tank into the ambient air. The remaining oxygen is delivered to the patient. On the next cycle, the air is directed into the second molecular sieve tank with the oxygen generated flushing the first tank and continuing the supply to the patient. This repetitive cycle generates the oxygen necessary to flush and prepare the saturated sieve tank while supplying the patient with a continuous flow of high concentration oxygen. Other options will include an Oxygen alarm and a pediatric flowmeter.

9.7 Indications for Use

The oxygen concentrators are intended to provide supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring

capabilities.

9.8 Technological Characteristics

The oxygen concentrator operates by using molecular sieve material to absorb water and nitrogen from filtered air. The resulting gas has an increased concentration of oxygen. This technology is well established and has been used in other legally marketed products. There are no major technological differences.

9.9 Performance Data

The Device meets the requirements of the FDA recognized standard covering Oxygen Concentrators, ASTM F 1464 - 93, and is substantially equivalent to the predicate devices.

9.9 Conclusion

Based on the design, performance specifications and testing and intended use, the Oxygen Concentrators are substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2001

Mr. Lee Leichter
Merits Health Products Co., Ltd.
c/o P/L Biomedical
7690 Cameron Circle
Fort Myers, FL 33912

Re: K011844
Merits Health Products Oxygen Concentrators
Regulation Number: 868.5440
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: June 4, 2001
Received: June 12, 2001

Dear Mr. Leichter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number: K011844

Device Name: Merits Health Products Oxygen Concentrator

Indications For Use: The Oxygen Concentrator is indicated for the delivery of supplemental oxygen in the home or medical institutions. The device is not intended for life support nor does it provide any patient monitoring capabilities.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011844

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.19)